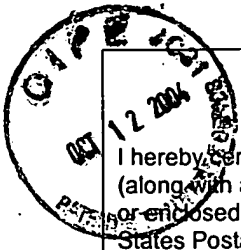


10/02/971

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Dulcie Donoso Fontt  
Dulcie Donoso-Fontt

**PATENT**

Applicant: **Naidu, A.S.**  
Patent No.: **6,797,266 B2**

Issued: **09/28/04**

Title: **PROBIOTIC COMPOSITIONS  
CONTAINING LACTOBACILLUS  
CASEI STRAIN ATCC PTA-  
3945**

Atty Docket No.: **51309-00002 (formerly  
14381.0012)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**Certificate  
OCT 19 2004  
of Correction**

**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT**

The Applicant respectfully requests that the Corrections Branch enter this request for Certificate of Correction to correct certain clerical errors occurring in the printed patent. The applicants assert that changes outlined in the Examiner's Amendment mailed June 2, 2004 with the Notice of Allowability in the above-identified patent were not included on the printed patent.

During prosecution of the above-identified patent, in a response to Office Action dated March 15, 2004, Applicant proposed the following amendment to claim 1:

1. (currently amended) A probiotic composition comprising Lactobacillus casei strain KE01 having ATCC accession number PTA-3945, wherein said Lactobacillus casei strain KE01 is derived from a [substantially] biologically pure culture.

On June 2, 2004, the Examiner, Deborah K. Ware, in an Examiner's Amendment entered after a May 21, 2004 telephone interview with Louis C. Cullman, attorney for Applicant, amended claim 1 as follows:

Claim 1, line 1, before "Lactobacillus" inserted -- a biologically pure culture of --  
, line 2, after PTA-3945" deleted ", wherein said",

OCT 20 2004

, line 3, deleted "Lactobacillus casei strain KE01 is derived from a biologically pure culture".

According to Examiner Ware's amendment, claim 1 should now read:

1. A probiotic composition comprising a biologically pure culture of Lactobacillus casei strain KE01 having ATCC accession number PTA-3945.

Claim 1 in issued U.S. Patent 6,797,266 does not read as amended by the Examiner, and therefore, Applicant respectfully requests that the Patent Office issue a Certificate of Correction to correct the Office's error with regard to claim 1.

The March 15, 2004 Response to Office Action, Notice of Allowability, Examiner's Amendment and Examiner-Initiated Interview summary mailed June 2, 2004 are enclosed. Applicants request that the attached Certificate of Correction be entered and that a copy be returned for Applicant's files.

Applicant believes that this error occurred in the Patent Office and that no fees are due. The Commissioner is hereby authorized to charge payment of any additional fees or credit any overpayment to Deposit Account No. 50-3207.

Respectfully submitted,

PRESTON GATES & ELLIS, LLP

Date

10/7/04

By:

  
LOUIS CULLMAN  
Attorney for Applicant  
Registration No. 39,645

Contact information below for inquiries regarding the above submission:

**Customer Number 45,200**

Louis C. Cullman  
Preston Gates Ellis LLP  
1900 Main Street, Suite 600  
Irvine, California 92614-7319  
(949) 253-0900 Telephone  
(949) 253-0902 Fax

Enclosures: Certificate of Correction; Copy of the Notice of Allowability, Examiner's Amendment and Examiner-Initiated Interview Summary; March 15, 2004 Response to Office Action

**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 6,797,266 *B2*  
DATED : September 28, 2004  
INVENTOR(S) : A. Satyanarayan Naidu

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the claims, claim 1, column 23, line 50, replace the text beginning with "1. A probiotic composition" and ending "biologically pure culture." with the following claim:

1. A probiotic composition comprising a biologically pure culture of *Lactobacillus casei* strain KE01 having ATCC accession number PTA-3945.

**MAILING ADDRESS OF SENDER:**

Preston Gates & Ellis, LLP  
1900 Main Street, Suite 600  
Irvine, CA 92614

**PATENT NO. 6,797,266 *B2***

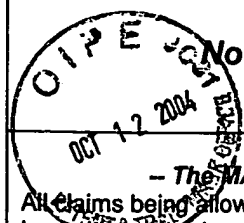
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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**OCT 20 2004**



# Notice of Allowability

Application No.	Applicant(s)	
10/021,871	NAIDU, A. SATYANARAYAN	
Examiner	Art Unit	
Deborah K. Ware	1651	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS  
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative  
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- ☒ This communication is responsive to 5/21/04.
- ☒ The allowed claim(s) is/are 1-33.
- ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - ☐ All
  - ☐ Some\*
  - ☐ None of the:
    - ☐ Certified copies of the priority documents have been received.
    - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
- ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 5/20/04
- ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

DAVID L. PITT  
PRIMARY EXAMINER  
ART UNIT 1651

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

#### In the title

Changed the title to – PROBIOTIC COMPOSITION CONTAINING  
*LACTOBACILLUS CASEI* STRAIN ATCC PTA-3945 – .

Authorization for this examiner's amendment was given in a telephone interview with Louis C. Cullman on May 21, 2004.

The application has been amended as follows:

#### In the abstract

At line 3, after "number" and inside the " \_\_\_\_\_ " inserted – PTA-3945-- .

#### In the claims

Claim 1, line 1, before "Lactobacillus" inserted –a biologically pure culture of-- ,

, line 2, after "PTA-3945" deleted ", wherein said",


, line 3, deleted "Lactobacillus casei strain KE01 is derived from a biologically pure culture" .


Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deborah K. Ware  
May 28, 2004

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128



PTO/SB/08A (08-03)  
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Substitute for form 1449A/PTO

Complete if Known

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	10/021,871
Filing Date	12-17-2001
First Named Inventor	Naidu, A. Satyanarayan
Group Art Unit	1651
Examiner Name	Ware, Deborah K.
Attorney Docket Number	14381-0012

Sheet 1 of 1

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>o</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
Stew		DE	2421088		Solco Basel AG	09-25-1976		
Stew		EP	0271364		Biorex CC	12-14-1987		
Stew		WO	9301823		Probi AB	02-04-1993		

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>

Examiner Signature	Deborah K. Ware	Date Considered	5/28/04
--------------------	-----------------	-----------------	---------

<sup>1</sup> YAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.4. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. <sup>6</sup> Name of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to the (and by the USPTO to process) and application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing, and submitting the completed application or to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, Patent and Trademark Office, US Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. EFND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<b>Examiner-Initiated Interview Summary</b>	<b>Application No.</b> 10/021,871	<b>Applicant(s)</b> NAIDU, A. SATYANARAYAN	
	<b>Examiner</b> Deborah K. Ware	<b>Art Unit</b> 1651	

**All Participants:**

(1) Deborah K. Ware.

(2) Louis Cullman.

**Status of Application:** \_\_\_\_\_

(3) \_\_\_\_\_

(4) \_\_\_\_\_

**Date of Interview:** 20 May 2004

**Time:** \_\_\_\_\_

**Type of Interview:**

- ☒ Telephonic  
☐ Video Conference  
☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

**Exhibit Shown or Demonstrated:** ☐ Yes ☒ No

If Yes, provide a brief description:

**Part I.**

**Rejection(s) discussed:**

*art rejections removed*

**Claims discussed:**

1-33

**Prior art documents discussed:**

*prior art removed*

**Part II.**
**SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:**

*Applicant's Representative authorized the examiner's amendment to put claims into condition for allowance. Also Applicant's Representative requested consideration of prior art cited in a search report of which a copy has been provided.*

**Part III.**

- ☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.  
☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

*Deborah K. Ware*

**DEBORAH K. WARE  
PATENT EXAMINER**

(Examiner/SPE Signature)

(Applicant/Applicant's Representative Signature – if appropriate)





# STRADLING YOCCA CARLSON & RAUTH

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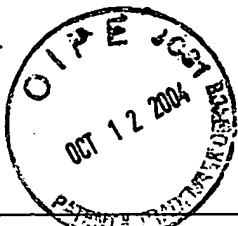
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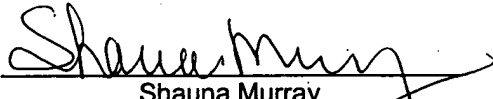
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Shauna Murray

**PATENT**

Applicant: **Naidu, A.S.**

Serial No.: 10/021871

Filed: 12/12/01

Title: Probiotic Compositions  
Derived from Lactobacillus  
casei Strain KE01

EXAMINER: WARE, DEBORAH K.

Group Art Unit: 1651

Atty Docket No.: 14381.0012 (formerly  
20424.12-11)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND REMARKS**

Dear Sir:

Responsive to the Office Action mailed September 23, 2003, Applicant responds as follows.

**Amendments to the Specification** are reflected in the listing of claims which begins on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 6 of this paper.

**Amendments to the Specification:**

Please make the following amendments to the specification, no new matter is being added.

At paragraph [0052] at line 2 please enter the following amendment: beginning at line 1, "The isolated Lactobacillus casei strain KE01 organism is maintained in a [substantially] biologically pure culture for use...."

At paragraph [0052] at line 3 please enter the following amendment: "As used herein '[substantially] biologically pure culture'...."

At paragraph [0053] at line five please enter the following amendment beginning at line 4 "...was derived from a [substantially] biologically pure culture."

### **Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-33 are presently pending. Please amend claims 1, 15, 20 and 28 as follows. No new matter has been added by these amendments.

#### **Claims as Presently Pending Following Entry of Amendments**

1. (currently amended) A probiotic composition comprising Lactobacillus casei strain KE01 having ATCC accession number PTA-3945, wherein said Lactobacillus casei strain KE01 is derived from a [substantially] biologically pure culture.
2. (previously amended) The probiotic composition according to claim 1 further comprising inert or active ingredients selected from the group consisting of carbohydrates, polypeptides, lipids, phytochemicals and combinations thereof.
3. (original) The probiotic composition according to claim 2 wherein said carbohydrate is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides and combinations thereof.
4. (original) The probiotic composition according to claim 3 wherein said carbohydrate is selected from the group consisting of trehalose, maltose, sucrose, dextrose, lactose, inulin, ribose and combinations thereof.
5. (original) The probiotic composition according to claim 3 wherein said disaccharide is trehalose dihydrate.
6. (original) The probiotic composition according to claim 3 wherein said oligosaccharide is fructo-oligosaccharide.
7. (original) The probiotic composition according to claim 3 wherein said polysaccharide is malt dextrin.

8. (original) The probiotic composition according to claim 2 wherein said polypeptide is selected from the group consisting of whey protein, egg albumin, gelatin, milk proteins, and combinations thereof.

9. (original) The probiotic composition according to claim 2 wherein said lipid is selected from the group consisting of soy bean oil, olive oil, palm kernel oil, peanut oil, walnut oil, canola oil and combinations thereof.

10. (original) The probiotic composition according to claim 2 wherein said phytochemical is selected from the group consisting of polyphenols, saponins, flavanoids, monoterpenes, allyl sulfides, lycopenes, carotenoids, polyactetylenes, silymarin, glycyrrhizin catechins and combinations thereof.

11. (original) The probiotic composition according to claim 1 further comprising trehalose.

12. (original) The probiotic composition according to claim 11 further comprising malt dextrin.

13. (original) The probiotic composition according to claim 11 further comprising fructo-oligosaccharide.

14. (original) The probiotic composition according to claim 13 wherein said Lactobacilli casei strain KE01 is present in the amount of approximately 10<sup>5</sup> to 10<sup>11</sup> colony forming units (CFU) per gram.

15. (currently amended) The probiotic composition according to [anyone] any one of claims 1 through 14 wherein said probiotic composition is a bolus, gel or liquid that is administered to an animal.

16. (original) The probiotic composition according to claim 15 wherein in said animal is selected from the group consisting of mammals, fish, birds, and reptiles.

17. (original) The probiotic composition according to claim 16 wherein said mammal is selected from the group consisting of humans, horses, dogs, cats, rabbits, sheep, swine, and cows.

18. (original) The probiotic composition according to claim 16 wherein said bird is selected from the group consisting of chickens, turkeys, pheasants, quail, parakeets, and parrots.

19. (original) The probiotic composition according to claim 15 wherein said bolus is selected from the group consisting of gelatin capsules, pressed tablets, and gel caps.

20. (currently amended) The probiotic composition according to claim 19 wherein said bolus is packaged in a polymer-lined foil pouch.

21. (previously amended) A probiotic composition comprising:

- powdered *Lactobacillus casei* strain KE01 having ATCC accession number PTA-3945 in the amount of from approximately 1 to 5 weight percent;
- a disaccharide from approximately 25 to 95 weight percent;
- an oligosaccharide from approximately 0 to 10 weight percent; and
- a polysaccharide from approximately 0 to 50 weight percent.

22. (previously amended) The probiotic composition of claim 21 wherein said powdered *Lactobacillus casei* strain KE01 having ATCC accession number PTA-3945 has approximately 10<sup>5</sup> to 10<sup>11</sup> CFU per gram and is present in the amount of approximately 3 weight percent.

23. (original) The probiotic composition of claim 21 wherein said disaccharide is present in the amount of approximately 62 weight percent.

24. (original) The probiotic composition of claim 21 wherein said oligosaccharide is present in the amount of approximately 5 weight percent.

25. (original) The probiotic composition of claim 21 wherein said polysaccharide is present in the amount of approximately 30 weight percent.

26. (original) The probiotic composition of claim 21 wherein said disaccharide is trehalose, said oligosaccharide is fructo-oligosaccharide and said polysaccharide is malt dextrin.

27. (previously amended) A probiotic composition comprising:

approximately 3 weight percent of powdered Lactobacillus casei strain KE01 having ATCC accession number PTA-3945 having approximately 105 to 1011 CFU per gram;

approximately 62 weight percent trehalose;

approximately 5 weight percent fructo-oligosaccharide; and

approximately 30 weight percent malt dextrin.

28. (currently amended) A method of inhibiting enteric pathogen disease in an animal comprising:

orally administering an effective amount of the probiotic compositions according to [anyone] any one of claims 1, 11, 12, 13, 20 or 26 to an animal in need thereof.

29. (original) The method according to claim 28 wherein said enteric pathogen is selected from the group consisting of enteropathogenic Escherichia coli (EPEC), enterotoxigenic E. coli (ETEC), Salmonella enteritidis, Yersinia pseudotuberculosis and Listeria monocytogenes.

30. (original) The method according to claim 28 wherein said animal is selected from the group consisting of mammals, fish, birds, and reptiles.

31. (original) The method according to claim 30 wherein said mammal is selected from the group consisting of humans, horses, dogs, cats, rabbits, sheep, swine, and cows.



32. (original) The method according to claim 30 wherein said bird is selected from the group consisting of chickens, turkeys, pheasants, quail, parakeets, and parrots.

33. (original) The method according to claim 28 wherein said administering step further comprises a probiotic compositions selected from the group consisting of gelatin capsules, pressed tablets, gel caps, animal feed and liquid beverages.

**REMARKS/ARGUMENTS:**

**November 4, 2003 Telephone Conference Summary**

The Applicant and his attorney of record wish to thank the Examiner for the courtesy extended during a telephonic interview conducted November 4, 2003. During the telephone conference the Examiner and the Applicant's attorney discussed claim rejections under 35 U.S.C. §112, first and second paragraphs and 35 U.S.C. §§ 102 (b) and 103 (a). This Response and Amendment is responsive to the remarks made by the Examiner and Applicant's attorney during the November 4, 2003 telephone conference. The following text that specifically identifies each issue discussed and the proposed amendment or remarks required to traverse the rejections of record.

Remarks regarding claim amendments.

Claim 1 was rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner states that the phrase "substantially pure culture" is unclear because the specification does not clearly define the intended meaning of substantially pure culture. During the telephonic interview on November 4, 2003 this rejection was discussed with Examiner Ware. The Applicant directed the Examiner's attention to paragraphs 52 and 53 and the specification and asserted that the meaning of "substantially pure" was clearly defined. However, the Examiner maintained her rejection based on the uncertainty inherent in the word "substantially." After discussion it was agreed that the term "biologically" pure would overcome the 35 U.S.C. § 112 second paragraph rejection and that the specification inherently supported the new

claim language. Thus claim 1 has been amended to read "biologically pure culture" and the Applicant respectfully asserts that this rejection has been traversed.

Claims 28 through 33 were rejected under 35 U.S.C. § 112 second paragraph because the recitation of "administering an effective amount of the probiotic composition" is vague. The Examiner states that it is unclear how the step of administering is to be carried out. The Applicant and the Examiner agreed that amending claim 28 to include the term "orally" before "administering" would traverse this rejection. Thus claim 28 has been amended appropriately.

Claims 15 and 18 were objected to due to a spelling error. Appropriate amendments to the claims have been made. "Anyone" has been replaced with "any one" as required. Thus this objection is traversed.

Claim 20 was objected to because the word "composition" does not follow probiotic in line 1 of claim 20. The appropriate amendment has been made to claim 20 adding the term "composition." Thus this objection is traversed.

#### **Remarks regarding amendment to the specification.**

The amendments are being made pursuant to recommendation of the Examiner based on discussions regarding same during the November 4, 2003 telephone conference. The Applicant attests that no new matter is being added to the specification by these amendments and that their sole purpose is to clarify and more specifically define the invention consistent with the claims and as suggested by the Examiner and her supervisor during the November 4, 2003 interview.

#### **Rejections under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claims 1-33 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that the present invention, a probiotic composition comprising a novel strain of

Lactobacillus casei, cannot be repeatedly isolated and therefore are not readily available to the public. The Examiner notes that the Applicants have made a deposit of their novel Lactobacillus casei strain, however, it is not clear from the specification that the deposit was made pursuant to the Budapest Treaty and has requested that an appropriate declaration of affidavit be made stating that the specific strain will be irrevocably and without restriction or condition be released to the public upon issuance of a patent.

Attached to this amendment is a statement by the attorney of record declaring that the deposit was made in accordance with the Budapest Treaty and the Applicant's specific strain will be irrevocably and without restriction or condition be released to the public upon issuance of a patent. Moreover, a copy of the American Type Culture Collection (ATCC) "International Form" and viability statement is also attached.

The Applicant respectfully asserts that the statement by the attorney of record and ATCC International Form traverse the Examiners 35 U.S.C. §112, first paragraph rejection.

**Prior Art Rejections under 35 U.S.C. §§102 (b) and/or 103 (a)**

The Examiner has rejected claims 1-6, 8, 11 and 13-19 under 35 U.S.C. §102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over WO 98/55131 (herein after WO '131).

The Applicant respectfully traverse the prior art rejections under 35 U.S.C. §§102 (b) and/or 103 (a) as anticipated by or in the alternative as obvious over WO 98/55131 (herein after WO '131) for the following reasons. WO '131 does not disclose the strain of Lactobacillus casei (KE01) as presently claimed.

The strain of Lactobacillus disclosed in WO '131 was isolated from infant feces, in contrast KE01 was isolated from a traditional fermented yogurt-like Asian dairy product (see the present specification at page seven, paragraph [0024] lines three). WO'131 repeatedly stresses that the source of the disclosed Lactobacillus sp. was isolated from a 5 day-old infant (page 9 line 37 of WO '131) and that it is "*very important*

*that the LB21 be isolated from the baby in the first week, such as from the first to eighth day, preferably on the fifth day of living.”* (see page 10 lines 2-4 of WO '131)

Furthermore, the cited prior art (WO'131) goes on to emphasize that “...*there is a great difference between different Lactobacillus strains, as is also the case in the subspecies Lactobacillus casei rhamnosus (LB21).* (See page 12 lines 28-30 of WO'131.)

Moreover, the WO'131 reference continues at page 13, lines 5-8 “*A great difference is, for instance, that LB21 has been isolated from the faeces of a baby....*”

Clearly, the WO'131 reference does not disclose the present invention which is Lactobacillus casei strain KE01 having ATCC accession number PTA-3945. The WO'131 reference does not teach isolating a Lactobacillus sp. having probiotic properties from yogurt. In fact WO'131 teaches away from isolating a probiotic organism from sources other than infant feces.

Therefore, because WO'131 does not disclose a probiotic Lactobacillus isolated from yogurt-like products and teaches only Lactobacillus sp. isolated from infant feces, WO'131 does not anticipate Lactobacillus' casei KE01, ATCC PTA-3945. Therefore, WO'131 does not anticipate claim 1 and thus cannot anticipate claims 2-20 which depend from claim 1. Thus the Applicant respectfully asserts that the Examiner's rejection under 35 U.S.C. §102 (b) is traversed.

Furthermore, the Applicant respectfully asserts that the 35 U.S.C. §1 103 (a) rejection of claims 1-6, 8, 11 and 13-19 as obvious in view of WO'131 is also traversed. As previously discussed, WO'131 teaches away from isolating probiotic compositions from sources other than infant feces. Thus one having ordinary skill in the art would not look to WO'131 for guidance in making the present invention, Lactobacillus casei strain KE01 having ATCC accession number PTA-3945 which was isolated from a yogurt-like product and shown by the present inventor to have excellent probiotic activity.

Moreover, WO'131 does not disclose all of the limitations of the pending claims, specifically, it does not disclose Lactobacillus casei strain KE01 having ATCC accession number PTA-3945.

Additionally persons having ordinary skill in the art would have to engage in undue experimentation without a reasonable probability of successfully isolating Lactobacillus casei strain KE01 based on the teaching of WO'131. For example at page 12 lines 28-30 of WO'131 "...there is a great difference between different Lactobacillus strains, as is also the case in the subspecies Lactobacillus casei rhamnosus (LB21). Furthermore, WO'131 states that "[t]he above-mentioned microorganism strain Lactobacillus casei rhamnosus LB21 was isolated as one of about hundred (sic) lactobacillus strains from feces of an approx. 5-day-old health baby ..." Clearly, WO'131 teaches that one of ordinary skill in the art would need to test hundreds of feces derived isolates in order to identify one having probiotic activity. The inherent unpredictability associated with successfully isolating probiotic organisms is also stated by the present inventor at page 13 paragraphs [0050] and [0051] wherein the present inventor describes testing 81 candidate probiotic lactobacilli before identifying ones having desirable characteristics. Moreover, this inherent unpredictability is recognized by the Examiner in her 35 U.S.C. §112 first paragraph rejection discussed *supra* wherein a biological deposit is required to enable the present invention.

Therefore, the WO'131 fails to establish a prima facie case of obviousness under the meaning of 35 U.S.C. § 103 (a) for the following reasons.

- 1) Persons having ordinary skill in the art seeking to isolate probiotic organisms from yogurt would not be motivated to seek the teachings of a reference (such as WO'131) stating it was essential to isolate probiotic organisms from human infant feces
- 2) There would be no probability of successfully isolating a probiotic organism from yogurt using a teaching stressing the difficulty in isolating a probiotic organism from feces (e.g. WO'131).
- 3) The WO'131 does not teach all of the limitations of the claimed invention. Specifically, it does not teach Lactobacillus casei strain KE01.

Therefore, the Applicant respectfully asserts that based on the foregoing arguments the 35 U.S.C. §103 (a) rejection has been traversed.

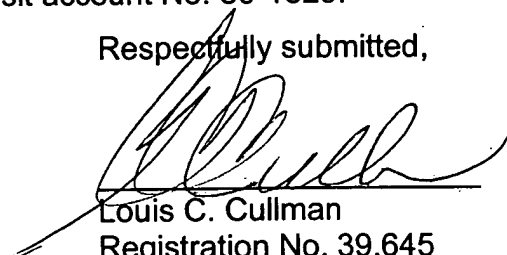
### Conclusion

The Applicant has amended the claims to comply with the Examiner's 35 U.S.C. §112, first and second paragraph rejections. Additionally, the Applicant's attorney of record has provided a statement that Lactobacillus casei strain KE01 PTA-3945 was deposited with the ATCC in accordance with the Budapest Treaty on Intellectual Property. Moreover, the Applicant respectfully asserts that the prior art rejections based on WO 98/55131 have been traversed (both under 35 U.S.C. §§ 102 (b) and 103 (a)). Therefore, the Applicant respectfully asserts that application is now in condition for immediate allowance and requests that Examiner allow this application to pass to issue.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1329.

Respectfully submitted,

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